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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,021

02/09/2005

Yoshiji Yamada

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EXAMINER

GREENE, JAIME M

ART UNIT

PAPER NUMBER

1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

03/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/524,021

Applicant(s)

YAMADA ET AL.

Examiner

Jaime M. Greene

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 5, 9, 13, drawn to a first invention involving genes selected from apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin.

Group 2, claim(s) 2, 6, 10, and 14, drawn to a second invention involving genes selected from thrombospondin 4, tumor necrosis factor-alpha, thrombomodulin, thrombopoietin, and platelet-activating factor acetylhydrolase.

Group 3, claim(s) 3, 7, 11, and 15, drawn to a third invention involving genes selected from E-selectin, fatty acid-binding protein 2, glycoprotein Ib-alpha, plasminogen activator inhibitor-1, paraoxonase, and apolipoprotein E.

Group 4, claim(s) 4, 8, 12, and 16 drawn to a fourth invention involving genes selected from plasminogen activator inhibitor-1, apolipoprotein C-III, paraoxonase, glycoprotein Ib-alpha, and apolipoprotein E

Note: see also election below.

2. The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: group 1 requires a combination of the genes Apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin, which are not

Art Unit: 1609

required for groups 2, 3, and 4. Therefore, there is no unity of invention between groups 1, 2, 3, and 4.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 5, 9, and 12 involve a set of 57 species.
Claims 2, 6, 10, and 13 involve another set of species.
Claims 3, 7, 11, and 14 involve another set of species.
Claims 4, 8, 12, and 15 involve another set of species.
The following claim(s) are generic: none.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons stated in the international search report provided by the Japanese Patent Office:

"First, discussion will be made on analyses of 2 or more polymorphisms selected from among the group consisting of (1) to (6) described in claim 1. Since analyses of 2 or more arbitrary polymorphisms selected from the group consisting of (1) to (6) are all involved in this case, the invention as set forth in claim 1 involves the step of analyzing 57 combinations of polymorphisms, namely, 15 combinations of 2 polymorphisms selected from among the 6 polymorphisms, 20 combinations of 3 polymorphisms and 1 combination of 6 polymorphisms. To regard that these 57 combinations of

Art Unit: 1609

polymorphisms fulfill the requirement of unity of invention, they should be so linked as to form a single general inventive concept. In other words, there should be a technical relevancy involving the same "special technical features" among these combinations. The expression "special technical features" as used herein means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over "the prior art" (see, if needed, PCT Rule 13.2). As stated in...the description of the present case, however, polymorphisms seemingly relating to restenosis after coronary angioplasty had been publicly known before the priority date of the present case. Accordingly, mere use of polymorphisms relating to restenosis after coronary angioplasty in diagnosing the risk, etc. cannot be considered as a "special technical feature". Even though the statement of the description of the present case is examined, any other "special technical feature" (for example, a technical feature that defines "all" of these 57 combinations enables more accurate risk diagnosis than the prior art) can be neither confirmed nor estimated. Such being the case, the 57 combinations of polymorphisms cannot be considered as a group of inventions so linked as to form a single general inventive concept. The same applies to 26 combinations of polymorphisms as described in claims 2 and 4 and 57 combinations of polymorphisms as described in claim 3. Therefore, it can be concluded that the present application has 166 inventions corresponding respectively to the 166 combinations of polymorphisms."

All of the claims involve a combination of 2 or more polymorphisms. There are 166 different combinations of polymorphisms, and each combination is considered as a separate species.

Applicant is required, in reply to this action, to elect a single species, corresponding to the elected invention, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jaime M. Greene whose telephone number is 571-270-3052. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1609

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMG 3/12/07



ZACHARIAH LUCAS
PATENT EXAMINER